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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/055,915      | 01/28/2002  | Shaun Jordan         | 01197.0227          | 1488             |

7590 12/15/2004

Finnegan, Henderson, Farabow,  
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Washington, DC 20005-3315

EXAMINER

SPIVACK, PHYLLIS G

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1614

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/055,915

**Applicant(s)**

JORDAN ET AL.

**Examiner**

Phyllis G. Spivack

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 3-19 and 23-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,20-22 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9-14-04</u> . | 6) <input type="checkbox"/> Other: _____  |

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Applicants' Request for Continued Prosecution (RCE) filed September 14, 2004 is acknowledged and accepted. Claims 1-32 are presented. Previously, claims 3-19 and 23-32 were withdrawn from consideration and ultimately canceled prior to the issuance of a Notice of allowance of claims 1, 20 and 22. The allowable subject matter was directed to the administration of the compound of instant formula 1 wherein the disorder of the central nervous system associated with 5-HT<sub>1A</sub> receptor subtype was limited to depression.

The election of depression on June 18, 2003, as the disorder of the central nervous system associated with the 5-HT<sub>1A</sub> receptor subtype, is still deemed proper. Accordingly, claims 1, 2, 20- 22 and 32 are presently under consideration wherein the disorder is depression. Those methods of use directed to disorders other than depression are presently withdrawn from consideration by the Examiner as directed to non-elected inventions.

An Information Disclosure Statement filed September 14, 2004 is further acknowledged and has been reviewed to the extent each reference is provided. The Mullins document was not scanned and is not part of the record.

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants are required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form.

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Claims 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

In view of the election of depression as the disorder of the central nervous system associated with 5-HT<sub>1A</sub> receptor subtype, claims 21 and 22 appear to be substantial duplicates.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 20-22 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banno et al., U.S. Patent 4,734,416.

Banno teaches the administration of the carbostyryl compound of instant formula 1 for treating anti-manic depressive psychosis. See formula 1, column one, in which instant formula 1 is encompassed. The claims differ in that the present claims broadly encompass any type of depression whereas the reference is restricted to the depressive component of manic depression psychosis. However, one skilled in the psychiatry art, in view of Banno's teaching, would have been motivated to administer a carbostyryl of formula 1 to treat various types of depression. Such would have been obvious in the absence of evidence to the contrary because the physiologic abnormality in the depressive condition relates to a disorder of 5-HT<sub>1a</sub> receptor subtype.

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached Monday to Friday from 10:30 AM to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Chris Low, can be reached at phone number 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-073-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Phyllis Spivack*  
Phyllis G. Spivack  
Primary Examiner  
Art Unit 1614

**PHYLLIS SPIVACK**  
**PRIMARY EXAMINER**

December 10, 2004